



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,191	06/14/2006	Burkhard Kroger	BGI-188US	2217
959	7590	02/09/2009	EXAMINER	
LAHIVE & COCKFIELD, LLP			LEAVITT, MARIA GOMEZ	
FLOOR 30, SUITE 3000				
ONE POST OFFICE SQUARE			ART UNIT	PAPER NUMBER
BOSTON, MA 02109			1633	
			MAIL DATE	DELIVERY MODE
			02/09/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/583,191	KROGER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 14 June 2006.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,2,5-48,51,52 and 54 is/are pending in the application.

4a) Of the above claim(s) 36-48 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1,2,5-35,51,52 and 54 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

*DETAILED ACTION*

Election/Restriction

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- I. Claim 1 and 5 drawn to **a method for regulating the transcription of a gene** comprising introducing into a host cell an isolated nucleic acid molecule having promoter activity, selected from the group consisting of a nucleic acid molecule comprising the nucleotide sequence **of SEQ ID NO:1** or homologs thereof.
- II. Claims 2, 6 and 7, drawn to an expression unit and a **method of regulating the expression of a gene** comprising introducing into a host cell an expression unit comprising a nucleic acid molecule having promoter activity comprising the nucleotide sequence **of SEQ ID NO:1** or homologs thereof, **wherein said nucleic acid molecule is functionally linked** to a nucleic acid sequence which ensures the translation of ribonucleic acids or **said expression unit consisting of SEQ ID NO:2**.
- III. Claims 1, 5, 8-12, 18, 19 drawn to **a method for altering the transcription rate of genes** in microorganisms compared with the wild type **comprising altering the specific promoter activity of a** nucleic acid molecule having promoter activity, comprising the nucleotide sequence **of SEQ ID NO:1** or homologs thereof **in the microorganism**, or regulating the transcription of genes in the microorganism by **introducing**, for example, **one or more genes** into the genome of the microorganism.
- IV. Claim 2, 6, 13-17, drawn to **a method for altering the expression rate of a gene** in microorganisms in microorganisms compared with the wild type **comprising altering**

**the specific promoter activity** comprising a nucleic acid molecule having promoter activity comprising the nucleotide sequence **of SEQ ID NO:1** or homologs thereof, **wherein said nucleic acid molecule is functionally linked** to a nucleic acid sequence which ensures the translation of ribonucleic acids or an expression unit **consisting of SEQ ID NO:2 and at least one additional nucleic acid.**

- V. Claims 2, 6, 7 and 20- 23 drawn an **expression cassette** comprising at least one expression unit comprising a nucleic acid molecule having promoter activity comprising the nucleotide sequence **of SEQ ID NO:1** or homologs thereof, **wherein said nucleic acid molecule is functionally linked** to a nucleic acid sequence which ensures the translation of ribonucleic acids or an expression unit **consisting of SEQ ID NO:2**.
- VI. Claims 1, 5, 24-28, drawn **a genetically modified microorganism**, where the genetic modification leads to an alteration or causing of the transcription rate of at least one gene compared with the wild type, and is dependent on altering the specific promoter activity in the microorganism of at least one endogenous nucleic acid having promoter activity of the nucleotide sequence **of SEQ ID NO:1** or homologs thereof
- VII. Claims 2, 6, 7, 20, 29-35, drawn **a genetically modified microorganism** wherein the modification leads to an alteration or causing of the expression rate of at least one gene compared with the wild type, and is dependent on altering the specific expression activity in the microorganism of at least one endogenous expression unit comprising a nucleic acid molecule having promoter activity comprising the nucleotide sequence **of SEQ ID NO:1** or homologs thereof, **wherein said nucleic acid molecule is functionally linked**

to a nucleic acid sequence which ensures the translation of ribonucleic acids or an expression unit **consisting of SEQ ID NO:2.**

VIII. Claims 51, 52 and 54 drawn **to an expression unit** which enables genes to be expressed in bacteria of the genus *Corynebacterium* or *Brevibacterium* comprising at least one of the nucleic acid sequences of SEQ ID NOs: 42, 43 or 44.

*Claim Objections*

Note that claims 36-48 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may depend from the previous claims in the alternative only and cannot depend from another multiply dependent claim. See MPEP § 608.01(n). Specifically, **claims 36 and 37**, depend from claims “24 to 35”, **claims 38** depends from claims “24 to 37”, **claims 39-40** depend from claims 24, 25, 31 or 32 and 31 depend from claims “29 or 30”, **claim 41** depends from claim 39 or 40, claim 39 depends from claims 24, 25, 31 or 32 and 31 depends from claims “29 or 30”, **claims 42 and 43** depend from claims 24, 25, 31 or 32 and 31 depend from claims “29 or 30”, **claim 44** depends from claim 42 or 43, claims 42 and 43 depend from claims 24, 25, 31 or 32 and 31 depend from claims “29 or 30”, **claims 45 and 46** depend from claims 24, 25, 31 or 32 and 31 depend from claims “29 or 30”, **claim 47** depends from claim 45 and 46 and 45 and 46 depend from claims 24, 25, 31 or 32 and 31 depend from claims “29 or 30”, and **claim 48** depends from claim 28 to 47. Accordingly, **claims 36 to 48** have not been further treated on the merits.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

“If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present”

37 CFR 1.475 (d) also states:

“If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)”.

The inventions listed as Groups I- VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking groups I-VIII appears to be that they all relate to compositions and methods comprising novel nucleic acid sequences for regulating the transcription and expression of genes, novel promoters and expression cassette units. However, prior art has taught a novel isolated nucleic acid from *Corynebacterium glutamicum* comprising a stress, resistance, or tolerance (SRT) gene used in a vector (II) for expression in a host cell used for diagnosing the presence or activity of *Corynebacterium diphtheriae* included in determination of SRT protein regions required for function, in modulating the SRT protein activity, and in modulating the activity of an SRT pathway (Pompejus et al., US Patent No 6,822,084, Date of Patent filing Jun. 23, 2000). Therefore, the technical feature linking the invention of groups I- VIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions of Groups I- VIII are drawn to materially different and distinct inventive concepts, having different chemical structures, physical properties and biological functions. For example, inventions of Group II, drawn to a method of regulating transcription of a gene, requires introducing in a host cell a nucleic acid having promoter activity comprising the nucleotide sequence of SEQ ID NO. 1 wherein said nucleic acid is functionally linked to a nucleic acid which ensures translation of ribonucleic acids or introducing an expression unit consisting of SEQ ID NO. 2 which is not disclosed as being required for Groups I. In addition, inventions of Group III require the regulation of the transcription of genes in a microorganism by nucleic acids having promoter activity comprising the nucleotide sequence of SEQ ID NO. 1 comprising the step of introducing one or more genes into the genome of the microorganism which is not required by the inventions of Groups I, II or IV. Moreover, inventions of Group IV are drawn to method of altering the expression rate of a gene by modifying a nucleic acid having promoter activity comprising the nucleotide sequence of SEQ ID NO. 1 wherein said nucleic acid is functionally linked to a nucleic acid which ensures translation of ribonucleic acids or introducing an expression unit consisting of SEQ ID NO. 2 comprising introducing one or more genes into the genome of the microorganism under the control of said promoter which is not disclosed as being required for Groups I, II or III. Furthermore, inventions of Groups V drawn to expression cassettes, invention of Group VIII drawn to expression units, and inventions of Groups VI and VII drawn to genetically modified microorganisms, are drawn to a single general

inventive concept that lacks the same or corresponding special technical features. For example, the genetically modified microorganism of Group VII requires altering the specific promoter activity in the microorganism of at least one endogenous nucleic acid having promoter activity of the nucleotide sequence of SEQ ID NO: 1 wherein said nucleic acid molecule is functionally linked to a nucleic acid sequence which ensures the translation of ribonucleic acids or an expression unit consisting of SEQ ID NO:2 which is not disclosed as being required for the genetically modified microorganism of Group VI.

The claims in Groups I- VIII are drawn to distinct products and methods that utilize distinct steps, requiring non-coextensive search and examination. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I- VIII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

MPEP 1893.03(d) states:

If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

### **Species restriction**

Should **Group III** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

**1) increasing the transcription rate, reducing the transcription rate** as recited in claims 10 and 12.

The species are independent or distinct because there methods for **the regulation of transcription rate** having different chemical structures, physical properties, and biological functions.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature of **regulation of transcription** in the microorganism , linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

If applicants elect the method of **increasing the transcription rate as recited in claim 10**, a further election of species is required from the following group as recited in claim 11.

**2a )** introducing one or more nucleic acids having promoter activity according to claim 1, where appropriate with altered specific promoter activity, into the genome of the microorganism so that transcription of one or more endogenous genes takes place under the control of the introduced nucleic acid having promoter activity according to claim 1, where appropriate with altered specific promoter activity,

**2b )** introducing one or more genes into the genome of the microorganism so that transcription of one or more of the introduced genes takes place under the control of the

Art Unit: 1633

endogenous nucleic acids having promoter activity according to claim 1, where appropriate with altered specific promoter activity,

**2c)** introducing one or more nucleic acid constructs comprising a nucleic acid having promoter activity according to claim 1, where appropriate with altered specific promoter activity, and functionally linked one or more nucleic acids to be transcribed, into the microorganism

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature of **increasing the transcription rate of a gene**, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 5, 2, 6, 8, 13, 20, 24, 29 and 51 are generic.

**3) a specifically named gene from the group recited in claim 18.**

The species are independent or distinct because there are **genes** having different chemical structures, physical properties, and biological functions.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature nucleic acids encoding a protein in the microorganism, linking the members do not constitute a special technical feature

as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 5, 2, 6, 8, 13, 20, 24, 29 and 51 are generic.

Should **Group IV** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

**4) increasing the specific expression rate activity of a gene, reducing the expression rate activity of a gene** as recited in claims 15 and 17.

The species are independent or distinct because there methods for **the regulation of expression of a gene** having different chemical structures, physical properties, and biological functions.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature **regulation of expression of a gene** in the microorganism , linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

If applicants elect the method of **increasing the specific expression rate activity of a gene as recited in claim 15**, a further election of species is required from the following group as recited in claim 16.

**5a )** introducing one or more expression units according to claim 2, where appropriate with increased specific expression activity, into the genome of the microorganism so that expression of one or more endogenous genes takes place under the control of the introduced expression units, where appropriate with increased specific expression activity,

**5b)** introducing one or more genes into the genome of the microorganism so that expression of one or more of the introduced genes takes place under the control of the endogenous expression units according to claim 2, where appropriate with increased specific expression activity,

**5c)** introducing one or more nucleic acid constructs comprising an expression unit according to claim 2, where appropriate with increased specific expression activity, and functionally linked one or more nucleic acids to be expressed, into the microorganism.

introducing one or more nucleic acids having promoter activity according to claim 1, where appropriate with altered specific promoter activity, into the genome of the microorganism so that transcription of one or more endogenous genes takes place under the control of the introduced nucleic acid having promoter activity according to claim 1, where appropriate with altered specific promoter activity,

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature of **increasing the specific**

**expression rate activity of a gene**, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 5, 2, 6, 8, 13, 20, 24, 29 and 51 are generic.

Should **Group V** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

**6) a specifically named gene from the group recited in claim 21.**

The species are independent or distinct because there are **genes** having different chemical structures, physical properties, and biological functions.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature nucleic acids encoding a protein in the microorganism, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 5, 2, 6, 8, 13, 20, 24, 29 and 51 are generic.

**7) a specifically named protein from the group recited in claim 22.**

The species are independent or distinct because there are **proteins** having different chemical structures, physical properties, and biological functions.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature nucleic acids encoding a protein in the microorganism, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 5, 2, 6, 8, 13, 20, 24, 29 and 51 are generic.

Should **Group VI or VII** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

**8) increasing the specific expression rate activity of a gene, reducing the expression rate activity of a gene** as recited in claims 26 and 28.

The species are independent or distinct because there methods for **the regulation of expression of a gene** having different chemical structures, physical properties, and biological functions.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature **regulation of expression of a gene** in the microorganism , linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

If applicants elect the method of **increasing the specific expression rate activity of a gene as recited in claim 26**, a further election of species is required from the following group as recited in claim 27.

**9a )** introducing one or more nucleic acids having promoter activity according to claim 1, where appropriate with increased specific promoter activity, into the genome of the microorganism so that transcription of one or more endogenous genes takes place under the control of the introduced nucleic acid having promoter activity, where appropriate with increased specific promoter activity,

**9b)** introducing one or more genes into the genome of the microorganism so that transcription of one or more of the introduced genes takes place under the control of the endogenous nucleic acids having promoter activity according to claim 1, where appropriate with increased specific promoter activity, and

**9c)** introducing one or more nucleic acid constructs comprising a nucleic acid having promoter activity according to claim 1

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature of **increasing the specific expression rate activity of a gene**, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 5, 2, 6, 8, 13, 20, 24, 29 and 51 are generic.

Should **Group VII** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

**10) increasing the specific expression rate activity of a gene, reducing the expression rate activity of a gene** as recited in claims 31 and 33.

The species are independent or distinct because there methods for **the regulation of expression of a gene** having different chemical structures, physical properties, and biological functions.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special

technical features for the following reasons: As the technical feature **regulation of expression of a gene** in the microorganism , linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

If applicants elect the method of **increasing the specific expression rate activity of a gene as recited in claim 31**, a further election of species is required from the following group as recited in claim 32.

**11a )** introducing one or more expression units according to claim 2, where appropriate with increased specific expression activity, into the genome of the microorganism so that expression of one or more endogenous genes takes place under the control of the introduced expression unit according to claim 2, where appropriate with increased specific expression activity,

**11b)** introducing one or more genes into the genome of the microorganism so that expression of one or more of the introduced genes takes place under the control of the endogenous expression units according to claim 2, where appropriate with increased specific expression activity,

**11c)** introducing one or more nucleic acid constructs comprising an expression unit according to claim 2,

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature of **increasing the specific expression rate activity of a gene**, linking the members do not constitute a special technical

feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 5, 2, 6, 8, 13, 20, 24, 29 and 51 are generic.

Should **Group VIII** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

**12) SEQ ID No 42, 43 and 44** as recited in claim 51.

The species are independent or distinct because there are having different chemical structures, physical properties, and biological functions.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical feature **nucleic acid** in the microorganism , linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search

Art Unit: 1633

queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include**

**(i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Maria Leavitt/

Maria Leavitt, Ph.D.  
Examiner, Art Unit 1633